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10/505,305	10/27/2004	Lionel Breton	112701-434	6006

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the spelling of “carotenoid” in claim

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group I, claims 1-10 and 25-30 directed to a lactic bacterial culture and a carotenoid on 1/19/07 is acknowledged. The claims are being examined to the extent that they are directed to a bacterial culture only.

Claims 1-10 and 25-30 are withdrawn from consideration to the extent that they pertain to supernatants. Claims 11-24 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of “a photoprotecting effective amount”, which is confusing. It is not clear whether skin or the food is to be photoprotected. In addition, it is not clear which components are required to be present in a photoprotecting effective amount.

Also, the phrase “at least one carotenoid or derivative” is not particularly defined in the specification. It is noted that at page 15, paragraph 5 applicant provides some examples of carotenoids and points out some sources of such carotenoids. However, it is not clear which compounds are encompassed “carotenoid derivatives in this context.

The claims 3 and 30 encompass an improper Markush grouping because they do not use the form “selected from the group consisting of A, B, AND C). The intervening “or” renders the claim indefinite as to what is intended. See MPEP 2173.05(h)(a).

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Claim 4 is confusing in that the genus species of the strains intended is not delineated with any specificity.

Claim 9 is vague and indefinite in the recitation “may be in a drinkable solution. This is not a positive recitation.

Claim 25 is vague and confusing in the recitation of “in a lyophilized powder attention”. It is unclear what is intended.

Claim 27 is confusing in indicating the carrier to be a “pharmaceutical product”. Generally carriers are identified as “pharmaceutically acceptable carriers”. The “product intended is not properly defined.

Claim 28 is confusing in that “tablets, liquid suspension, dried oral supplements, wet oral supplements and dry-tube-feeding” are not generally deemed “a food”.

Claim 28 fails to find proper antecedent basis in claim 7 for “pharmaceuticals carrier”. Claim 7 recites “the carrier”.

Claim 28 is confusing in the recitation of “dry-tube-feeding” since it is unclear that this material properly constitutes a “carrier”

Claim 28 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over of claim 9 of copending, currently commonly owned Application No. 10/505,285, which shares two inventors with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant application is completely encompassed by the scope of the claims in the '305 application.

Instant claims are drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and carotenoid or derivatives thereof. Claim 9 of the '305 application is drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at least one carotenoid or derivative thereof and a yeast. Because claim 1 of the instant application uses open-claim language ("comprising"), this claim is fully encompassed by compositions comprising the two components of the '285 claim plus any other additional component. The generic nature of claim 9, which does not place any restrictions on the type or number of probiotic bacteria or carotenoids, or the physical form of the food composition, encompasses the specific claims of the instant application (2-10, 25-30).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10 and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 22-32 of copending, currently commonly owned Application No. 10/504,906, which shares two inventors with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant application completely encompasses the scope of the claims in the '906 application.

The instant claims are drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and carotenoid or derivatives thereof. Claim 1 of the '906 application is drawn to a composition comprising a photoprotecting effective

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amount of at least one probiotic lactic acid bacterium, and at least one yeast. The instant claims fully encompass claims to compositions comprising the probiotic '906 claim plus any other additional component such as a carotenoid producing yeast or a pharmaceutical product containing yeast..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10 and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending, Application No. 11/159198, which shares at least one inventor with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending applications are directed to the use of probiotic bacteria in cosmetic compositions which include the same strains, such as *L. johnsonii* CNCM I-1125, *L. paracasei* CNCM I-1126 and *Bifidobacterium longum* CNCM I -2170. The cosmetic compositions of the copending application would be expected to be photoprotective at least to some extent.

Therefore, the claims are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strains of bacteria. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if all of the starting materials were readily available to the public at the time of invention.

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It appears that a deposit was made in this application as filed as noted on page 15 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the

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availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 5-7, 9-10, 25-26, 28, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Cavaliere Vesely *et al.* (EP 1020123)

The claims are directed to an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier.

Cavaliere Vesely *et al.* disclose an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier. See, e.g., Examples 1-3.

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Claims 1-2, 5-7, 9-10, 25-26, 28, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Shields, Jr. *et al.* (U.S. Patent 6,156,355).

The claims are directed to an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier.

Shields, Jr. *et al.* disclose an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier.

See, e.g., Example 5.

Claims 1,2,5,6,7,10, 15, 26, 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Runge *et al.* (U.S. Patent No. 7,037,708).

The claims are directed to an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier.

Runge *et al.* disclose an orally administrable composition including a food composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier. See, e.g., Example S2. The dried mixture comprises *Lactobacillus plantarum* and at least β -carotene in powder form, wherein the ingestible carrier is maltodextrin. This material is orally administrable and constitutes a food composition.

Claims 1-2, 5-7, 9-10, 25-26, 28, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Berggren *et al.* (WO/00/79072)

The claims are directed to an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier.

Berggren *et al.* disclose an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier.

See, e.g., Examples 2-4.

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Claims 1-10 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Vesely *et al.* (EP 1020123) taken with Shields, Jr. *et al.* (U.S. Patent 6,156,355), Runge *et al.* (U.S. Patent No. 7,037,708), by Berggren *et al.* (WO/00/79072) and Brassart *et al.* (U.S. Patent No. 5,603,930)

The claims are directed to an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier.

AS discussed *supra*, the cited references disclose an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier.

The references differs from the claimed invention in that the specific strains of claim 4 are not disclosed and in the provision of milk products, milk based fermented products such as yogurt.. However, Brassart *et al.* adequately demonstrates that at least strains CNCM I-1225 and CNCM I-1226 are old and well known in the art as probiotics. In addition the reference demonstrates that the composition is provided as a yogurt a milk-based fermented product. See, e.g., col. 3, lines 55-60.

The nature of the carrier as a pharmaceutical product is unclear. However, it is submitted that the yogurt containing strain CNCM I-1225 comprises a pharmaceutical product as a carrier, in the absence of evidence to the contrary.

The concentrations discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of concentrations for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the products of Cavaliere Vesely *et al.*, Shields, Jr. *et al.*, Runge *et al.* and Berggren *et al.* by providing a composition comprising a photoprotective amount of probiotic strains CNCM I-1225 and CNCM I-1226 as suggested by the teachings of Brassart *et al.* for the expected benefit of providing a healthful composition comprising a

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probiotic strain known to have favorable effects against disease and carotenoids such as β -carotene known to have at least antioxidant effects.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
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Art Unit 1651